Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • May 2017

Cleveland Clinic Laboratories is dedicated to keeping you updated and informed about recent testing changes. This Technical Update is provided on a monthly basis to notify you of any changes to the tests in our catalog.

Recently changed tests are bolded, and they could include revisions to methodology, reference range, days performed, or CPT code. Deleted tests and new tests are listed separately. For your convenience, tests are listed alphabetically and order codes are provided.

To compare the new information with previous test information, refer to the online Test Directory at clevelandcliniclabs.com. Test information is updated in the online Test Directory on the Effective Date stated in the Technical Update. Please update your database as necessary.

For additional detail, contact Client Services at 216.444.5755 or 800.628.6816, or via email at clientservices@ccf.org.

Test Update Page #	Summary of Changes by Test Name	Order Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT	Fee
3	5-Fluorouracil Toxicity, Chemo Response, 5 Mut						■						■	
3	AFB Culture Only						■							
3	AFP – Amniotic Fluid						■	■			■			
3	Alkaline Phosphatase Isoenzymes							■						
11	Alpha Globin (HBA1 & HBA2) Sequencing					■								
3	Aluminum						■				■			
3	Aluminum, Urine 24 Hour										■			
3	Bacterial Vaginosis Scored Gram Stain							■						
3	Bacterial Vaginosis Scored Gram Stain & Candida Smear							■						
10	Carbapenem Resistance Gene PCR				■									
10	Chromosome Analysis with Reflex AML FISH panel				■									
4	CMV by PCR, CSF/FLD/Tissue/Bone Marrow		■				■	■				■		
11	CMV PCR, Bone Marrow					■								
4	Cortisol, Free		■				■							
10	FISH for Aggressive B-Cell Lymphoma on Bone Marrow or Blood				■									
11	FISH for BCL2 on Bone Marrow or Blood				■									
4, 11	G-6-PD Quantitative						■	■			■	■		■
4	HIV Quant RNA by PCR							■						
5	IDH1/IDH2 Mutation, Blood/Bone marrow						■	■				■		
11	IDH1/IDH2 Mutation, FFPE Tissue				■									

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5	JAK2 V617F Mutation Detection								■					
5	JC Virus by PCR					■								
5	Lactic Acid, Body Fluid					■	■				■	■		
5	LDLR Hypercholesterolemia Sequencing		■			■	■		■	■	■	■		
6	Melatonin					■				■				
6	MLH1 Promoter Hypermethylation					■								
6	MPL Mutation Analysis								■					
6	Mycobacterium tuberculosis Complex and Rifampin Resistance by PCR					■	■							
6	Nucleophosmin Gene (NPM1) Mutation								■					
11	Platelet Antibody Screen				■									
6	PTH Intact, Fluid					■	■							
7	Recombx CV2 Autoantibody Test					■	■				■	■		
7	Recombx MaTa Autoantibody Test					■	■				■	■		
7	Tay-Sachs (Hexosaminidase)					■	■				■		■	
7	Thyroglobulin, FNA					■								
8	Thyroxine, Fr by Eq Dialysis/HPLC-TndmMS					■	■							
8	Toxoplasmosis, IgG Antibody					■								
8	Toxoplasmosis IgM					■								
8	Toxoplasmosis IgM and IgG, Ab					■								
8	Trypsinogen					■	■				■			
8	Vaginal Smear for Candida						■							
8	Vitamin B1, Plasma						■							
8	Vitamin B1, Whole Blood						■							
9	Vitamin B6					■	■					■		

Test Changes

Test Name	Order Code	Change	Effective Date
5-Fluorouracil Toxicity, Chemo Response, 5 Mut	5FLUO	**Special Information: This test is New York DOH approved.** **Clinical Information: Predict risk of dose-related toxicity and responsiveness to 5-FU therapy.** **CPT:** 81400 x 1, 81401 x 1	5/15/17
AFB Culture Only	AFCO	**Special Information:** An AFB stain will not be performed. Patient Preparation: For blood cultures, select vein to use. Wipe off venipuncture site using a 70% alcohol pad. Apply Chloraprep to the skin over the selected venipuncture site and apply using up and down and back and forth strokes for a full 30 seconds. Allow the site to dry completely for 30–60 seconds. Swab septum of Isolator tube or Myco/F bottle **using 70% alcohol.** Draw 10 mL into adult Isolator tube, 1.5 mL into Pediatric Isolator tube or 5 mL if direct draw into the Myco/F bottle. After inoculation, clean septum with **70%** alcohol. Transport to Microbiology within 4–6 hours is recommended. Do NOT transport glass Myco/F bottles using the pneumatic tube system.	5/4/17
AFP–Amniotic Fluid	FAFPAM	**Clinical Information: Evaluate possibility of a fetal open** neural tube defect **at 13-36 weeks of gestation.** **Specimen Requirement:** 2.5 mL amniotic fluid in a clean container; Minimum: 1.5 mL; Include gestational age at the time of collection or estimated due date; **Submit Patient History for Prenatal Cytogenetics form, available through Client Services at 800.628.6816 or 216.444.5755;** Ambient **Reference Range:** AFP Amniotic Fluid Result: Refer to report AFP Amniotic Fluid Gest Age: Refer to report AFP Amniotic Fluid MoM: Refer to report AFP Amniotic Fluid Interpretation: Refer to report; **Ranges are based upon the weeks of gestation; Multiple of median: 1.99 or less**	5/15/17
Alkaline Phosphatase Isoenzymes	ALKISO	**Specimen Requirement:** 2 mL serum from a serum separator (gold) tube; Minimum: 1 mL; **Refrigerated**	Effective immediately
Aluminum	ALUM	**Clinical Information:** Serum aluminum may be useful in the assessment of aluminum toxicity due to dialysis and is the preferred test for routine screening. Serum aluminum **> 50.0 µg/L** is consistent with overload and may correlate with toxicity. **Reference Range:** 0–99 Years: **0.0–15.0 µg/L**	5/15/17
Aluminum, Urine 24 Hour	UAL24	**Reference Range:** 0–99 Years: **0.0–7.0 µg/L**	5/15/17
Bacterial Vaginosis Scored Gram Stain	BVSTN	**Specimen Requirement:** Vaginal swab; **Culturette swab in non-nutritive transport medium (e.g., Amies or Stuart's);** Minimum: Unspecified; Ambient	5/4/17
Bacterial Vaginosis Scored Gram Stain & Candida Smear	BVCNSM	**Specimen Requirement:** Vaginal swab; **Culturette swab in non-nutritive transport medium (e.g., Amies or Stuart's);** Ambient	5/4/17

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
CMV by PCR, CSF/FLD/Tissue/Bone Marrow	CMVCSF	**Test Name:** Previously CMV by PCR, CSF/FLD/Tissue **Special Information:** Specimen source is required. **Unacceptable conditions: Heparinized specimens. This test is New York DOH approved.** **Clinical Information: Detects cytomegalovirus but does not quantify viral load.** **Specimen Requirement:** 1 mL cerebrospinal fluid (CSF) in a sterile container; Minimum: 0.5 mL; Frozen *OR* 1 mL ocular fluid in a sterile container; Minimum: 0.5 mL; Frozen *OR* Tissue in a sterile container (snap frozen); Frozen *OR* 1 mL bronchoalveolar lavage (BAL) in a sterile container; Minimum: 0.5 mL; Frozen *OR* 1 mL random urine in a sterile container; Minimum: 0.5 mL; Frozen *OR* **1 mL bone marrow in an EDTA lavender top tube;** Minimum: 0.5 mL; **Send specimen in EDTA lavender tube or sterile container; Refrigerated** *OR* **1 mL amniotic fluid in a sterile container;** Minimum: 0.5 mL; Frozen **Stability:** Ambient: **Bone marrow: 1 week;** Tissue: Unacceptable; Other specimen types: 8 hours Refrigerated: **Bone marrow: 1 week;** Tissue: Unacceptable; Other specimen types: **72 hours** Frozen: **Bone marrow: 1 week;** Tissue: 3 months; Other specimen types: 3 months	5/15/17
Cortisol, Free	FRCORT	**Test Name:** Previously Cortisol, Free Serum **Special Information: Indicate time of draw on test request form and specimen tube.** Grossly hemolyzed, **icteric, lipemic or heparinized specimens are unacceptable. This test is New York DOH approved.** **Clinical Information: Screen, diagnose, and monitor diseases associated with excess or deficient cortisol production.** To convert to nmol/L, multiply μg/dL by 27.6.	Effective immediately
G-6-PD Quantitative	G6PDQT	**Clinical Limitation: This assay has a reduced sensitivity for detection of glucose-6-phosphate dehydrogenase deficiency during an acute hemolytic episode, with increased reticulocytes, or after blood transfusion.** **Clinical Information: Glucose-6-phosphate dehydrogenase (G6-PD) deficiency is an X-linked recessive condition associated with variably severe hemolytic anemia. Patients with severe enzyme deficiencies typically show < 10% of the normal mean enzyme levels. Levels from 10%–60% of normal may be seen in mild to moderate deficiency, or in female carriers.** **Specimen Requirement:** 3 mL whole blood in an EDTA lavender top tube; Minimum: 1.5 mL; Refrigerated **Reference Range: 8.6–18.0 U/g Hb** **Days Performed: Monday–Friday, excluding major holidays** **Reported:** 2–3 days	7/11/17
HIV Quant RNA by PCR	HIVRNA	**Specimen Requirement:** 3 mL plasma from an EDTA (white) plasma preparation tube (PPT); Minimum: **3 mL;** Centrifuge within **24** hours of collection; Do not aliquot; Refrigerated *OR* 3 mL plasma from an EDTA lavender top tube; Minimum: **3 mL;** Separate plasma from whole blood within 24 hours of collection by centrifugation and transfer to a sterile screw–cap polypropylene tube; Refrigerated	6/20/17

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
IDH1/IDH2 Mutation, Blood/ Bone marrow	IDH12	**Special Information: Unacceptable conditions: Serum or plasma. Specimens collected in anticoagulants other than EDTA. Clotted or grossly hemolyzed specimens.** **Clinical Information: Detect IDH1 and IDH2 mutations in whole blood or bone marrow. May have prognostic significance in patients with hematologic malignancies, depending on the clinical and genetic context.** **Specimen Requirement:** 5 mL whole blood in an EDTA lavender top tube; Minimum: 1 mL; Refrigerated *OR* 3 mL bone marrow in an EDTA lavender top tube; Minimum: 1 mL; Refrigerated *OR* Extracted DNA; 20 µL extracted DNA at a concentration of 50 ng/µL is required; Refrigerated **Stability:** Ambient: 24 hours Refrigerated: 5 days Frozen: Unacceptable **Days Performed: Sunday, Tuesday, Thursday** **Reported:** 13–**18** days	5/15/17
JAK2 V617F Mutation Detection	JAK2	**Methodology: Next Gen Sequencing**	Effective immediately
JC Virus by PCR	JCPCRB	**Special Information: Must indicate source of specimen.**	Effective immediately
Lactic Acid, Body Fluid	BFLACT	**Special Information:** Collect on ice. Centrifuge and separate **to remove cellular material.** Indicate body fluid source/type on test request form. **Unacceptable conditions: Specimens other than those listed. This test is New York DOH approved.** **Clinical Information: Reference ranges for this assay have not been established for body fluid. Results should be interpreted in comparison to the lactic acid concentration in blood and in conjunction with clinical context.** **Specimen Requirement:** 1 mL **peritoneal fluid** in a **clean** container; Minimum: 0.2 mL; Collect on ice; **Centrifuge and separate to remove cellular material;** Indicate source on test request form; **Transport 1 mL fluid in a standard transport tube;** Frozen *OR* 1 mL **synovial fluid** in a **clean** container; Minimum: 0.2 mL; Collect on ice; **Centrifuge and separate to remove cellular material;** Indicate source on test request form; **Transport 1 mL fluid in a standard transport tube;** Frozen **Stability:** Ambient: Unacceptable Refrigerated: **2 weeks** Frozen: 1 month **Days Performed:** Sunday–Saturday **Reported:** 2–**3** days	5/15/17
LDLR Hyper-cholesterolemia Sequencing	LDLR	**Test Name:** Previously Hypercholesterolemia (LDLR) Evaluation **Special Information: Informed consent is required. Higher blood volumes ensure adequate DNA quantity, which varies with WBC, specimen condition, and need for confirmatory testing. Patients, 0–3 years, have higher WBC, yielding more DNA per mL of blood.** **Specimen Requirement: 8 mL** whole blood in an **EDTA lavender top tube;** Minimum: **6 mL for adults, 1 mL for pediatric samples; Note: Pediatric preferred volume is 2 mL;** Ambient **Stability:** Ambient: **10 days** Refrigerated: **10 days** Frozen: Unacceptable **Methodology: Sanger Sequencing** **Reference Range:** No **sequence variation** detected **Days Performed: Varies** **Reported: 15–29** days	6/29/17

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Melatonin	MELAT	**Special Information: Unacceptable conditions: Serum separator tube. Hemolyzed or lipemic specimens.** Research Use Only. **This test is New York DOH approved.** **Reference Range:** **Adults** **Daytime: 3.4–53.9 pg/mL** **Nighttime: 7.1–89.5 pg/mL**	5/15/17
MLH1 Promoter Hypermethylation		**Clinical Limitation:** MLH1 Promoter Assay detects hypermethylation in a region from **-209** to -181 bases from the transcription start site of the promoter of the MLH1 gene. It does not detect methylation in other areas of the MLH1 promoter. **Clinical Information:** Hypermethylation of the promoter of MLH1 in tumor tissue can **inform differentiation of** sporadic **from** hereditary **tumors** and guide further testing.	Effective immediately
MPL Mutation Analysis	MPL	**Methodology: Next Gen Sequencing**	Effective immediately
Mycobacterium tuberculosis Complex and Rifampin Resistance by PCR	MTBAM1	**Special Information:** Specimen source required. To perform this test it is essential to know whether or not the submitted specimen has been processed (digestion and decontamination procedure). If processed, smear results must be provided as a comment on the test order or requisition. **For processed specimens, identify method used for digestion.** Delayed turnaround time will occur if the required information is not provided. **Unacceptable conditions: Blood, paraffin blocks, stool, swabs, tissue, and urine. NOTE: Body Fluids other than pleural fluid will be run with a disclaimer. This test is New York DOH approved.** **Clinical Information: Panel includes PCR testing to detect M. tuberculosis complex isolates and determine possible resistance to rifampin treatment. Test may be ordered for client-processed specimens.** **Specimen Requirement:** 10 mL **respiratory specimens, cerebrospinal fluid (CSF) or pleural fluid** in a sterile container; Minimum: 1 mL; Unprocessed specimen: **Send 5–10 mL specimen; MUST label as unprocessed;** Indicate specimen source; Refrigerated *OR* 5 mL **respiratory specimens, cerebrospinal fluid (CSF) or pleural fluid** in a sterile container; Minimum: 1 mL; Processed specimen: **Send 2**–5 mL digested/decontaminated specimen; Identify method used for digestion *AND* provide smear results; **Place each specimen in an individually sealed bag; MUST label as processed; Indicate specimen source;** Refrigerated	5/15/17
Nucleophosmin Gene (NPM1) Mutation	NPM1	**Methodology: Next Gen Sequencing**	Effective immediately
PTH Intact, Fluid	FLPTH	**Special Information: Unacceptable conditions: Specimen types other than those listed. Specimens too viscous to be aspirated by the instrument. Indicate source on test request form.** **Clinical Information: Aid in the differentiation of parathyroid tissue from thyroid tissue.** **Specimen Requirement:** 0.5 mL fine needle aspirate (FNA) in a clean container with saline; Minimum: 0.5 mL; Specimen must be non-viscous and free of particulate matter; Centrifuge to remove cellular material; Indicate source of specimen; **Transfer 0.5 mL saline needle rinse to a standard transport tube;** Frozen *OR* 0.5 mL body fluid in an EDTA lavender top tube; Minimum: 0.5 mL; Specimen must be non-viscous and free of particulate matter; Centrifuge to remove cellular material; Indicate source of specimen; Frozen *OR* 0.5 mL body fluid in a lithium heparin green top tube; Minimum: 0.5 mL; Specimen must be non-viscous and free of particulate matter; Centrifuge to remove cellular material; Indicate source of specimen; Frozen *OR* 0.5 mL body fluid in a sodium heparin green top tube; Minimum: 0.5 mL; Specimen must be non-viscous and free of particulate matter; Centrifuge to remove cellular material; Indicate source of specimen; Frozen	5/15/17

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Recombx CV2 Autoantibody Test	CV2	**Special Information: Rejection criteria: Gross hemolysis; grossly lipemic; grossly icteric; turbid; bacterial contamination. Serum must be separated from whole blood within 48 hours of collection.** **Clinical Information: Anti-CV2 antibody can be detected in patients with paraneoplastic neurological syndromes that include the acute or subacute onset of a sensory neuropathy, limbic encephalitis, encephalomyelitis, chorea, or cerebellar degeneration.** **Specimen Requirement:** 2 mL serum from a red top tube with no additive; Minimum: 0.5 mL; **Serum must be separated from whole blood within 48 hours of collection;** Refrigerated *OR* 2 mL cerebrospinal fluid (CSF) in a sterile container; Minimum: 0.5 mL; Refrigerated *OR* **2 mL serum from a serum separator (gold) tube;** Minimum: 0.5 mL; **Serum must be separated from whole blood within 48 hours of collection;** Refrigerated **Stability:** Ambient: 72 hours **(serum and CSF)** Refrigerated: **28** days **(serum and CSF)** Frozen: **Serum: 1 year; CSF: 28 days** **Days Performed: Monday–Friday** **Reported: 4–10** days	Effective immediately
Recombx MaTa Autoantibody Test	MATA	**Special Information: Rejection criteria: Gross hemolysis; grossly lipemic; grossly icteric; turbid; bacterial contamination. Serum must be separated from whole blood within 48 hours of collection.** **Clinical Information: Anti-Ma and anti-Ta antibodies can be detected in patients with a wide range of paraneoplastic neurological syndromes including acute or subacute onset of symptoms of limbic encephalitis, brainstem encephalitis, cerebellar degeneration, or polyneuropathy.** **Specimen Requirement:** 2 mL serum from a red top tube with no additive; Minimum: 0.5 mL; **Serum must be separated from whole blood within 48 hours of collection;** Refrigerated *OR* 2 mL cerebrospinal fluid (CSF) in a sterile container; Minimum: 0.5 mL; Refrigerated *OR* **2 mL serum from a serum separator (gold) tube;** Minimum: 0.5 mL; **Serum must be separated from whole blood within 48 hours of collection;** Refrigerated **Stability:** Ambient: 72 hours **(serum and CSF)** Refrigerated: **28** days **(serum and CSF)** Frozen: **Serum: 1 year; CSF: 28 days** **Days Performed: Monday–Friday** **Reported: 4–10** days	Effective immediately
Tay-Sachs (Hexosaminidase)	HEX	**Special Information:** This test cannot be performed on pregnant women. **Patient must be fasting (4 hours). This test is New York State approved. New York clients must provide informed consent. Physician's name and phone number are required.** **Clinical Information:** Used to screen for Tay-Sachs in the male and non-pregnant female. **This test is the recommended test for diagnosis and carrier testing for the B1 variant of Tay-Sachs disease and is performed on serum using the natural substrate. It should not be ordered as a first-line test.** **Specimen Requirement:** 1 mL serum from a **red top tube with no additive;** Minimum: **0.15 mL;** Patient **must** fast for 4 hours prior to collection; Frozen *OR* 1 mL serum from a **serum separator (gold) tube;** Minimum: **0.15 mL;** Patient **must** fast for 4 hours prior to collection; Frozen **Days Performed: Varies** **Reported: 4–7 weeks** **CPT: 83080 x 1**	Effective immediately
Thyroglobulin, FNA	FTHYG	**Special Information:** Use with FNA biopsy of thyroid nodules to diagnose benign or malignant non-medullary thyroid nodules. **Unacceptable conditions: Specimen types other than those listed. Specimens containing EDTA. Viscous specimens. Indicate source on test request form. This test is New York DOH approved.**	5/15/17

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Thyroxine, Fr by Eq Dialysis/HPLC-TndmMS	T4HPLC	**Special Information:** This test is not recommended for routine evaluation of thyroid disorders. **Unacceptable conditions: Plasma. This test is New York DOH approved.** **Specimen Requirement:** 2 mL serum from a red top tube with no additive; Minimum: 0.3 mL; **Separate from cells ASAP or within 2 hours of collection and aliquot into a standard transport tube;** Refrigerated *OR* **2 mL serum from a serum separator (gold) tube;** Minimum: 0.3 mL; **Separate from gel ASAP or within 2 hours of collection and aliquot into a standard transport tube;** Refrigerated	5/15/17
Toxoplasmosis, IgG Antibody	TOXG	**Note:** *This test was previously announced in the April 2017 Technical Update. Instead of 5/31/17, changes for this test will go live on* ***5/3/17****.*	**5/3/2017**
Toxoplasmosis IgM	TOXMAB	**Note:** *This test was previously announced in the April 2017 Technical Update. Instead of 5/31/17, changes for this test will go live on* ***5/3/17****.*	**5/3/2017**
Toxoplasmosis IgM and IgG, Ab	TOXMG	**Note:** *This test was previously announced in the April 2017 Technical Update. Instead of 5/31/17, changes for this test will go live on* ***5/3/17****.*	**5/3/2017**
Trypsinogen	TRYPSI	**Special Information: Causes for rejection: Hemolysis, grossly lipemic samples, and samples containing radioactive compounds such as those from patients who have undergone in-vivo radioisotope testing. This test is not available for New York patient testing.** **Specimen Requirement:** 1 mL serum from a red top tube with no additive; Minimum: 0.5 mL; **Ambient** *OR* **1 mL serum from a serum separator (gold) tube;** Minimum: 0.5 mL; **Ambient** **Days Performed:** Sunday, Wednesday **Reported:** 3–**10** days	Effective immediately
Vaginal Smear for Candida	CANSTN	**Specimen Requirement:** Vaginal swab; **Culturette swab in non-nutritive transport medium (e.g., Amies or Stuart's);** Minimum: Unspecified; Ambient	5/4/17
Vitamin B1, Plasma	PVITB1	**Specimen Requirement:** 1 mL plasma from a sodium or lithium heparin green top tube; Minimum: 0.2 mL; Separate plasma from cells within 1 hour of collection; Transfer 1 mL plasma to a **standard false-bottom aliquot tube; Note: Orange-capped tubes are not acceptable;** Separate specimens must be submitted when multiple tests are ordered; Frozen *OR* 1 mL plasma from an EDTA lavender top tube; Minimum: 0.2 mL; Separate plasma from cells within 1 hour of collection; Transfer 1 mL plasma to a **standard false-bottom aliquot tube; Note: Orange-capped tubes are not acceptable;** Separate specimens must be submitted when multiple tests are ordered; Frozen *OR* **1 mL plasma from a lithium heparin (light green) plasma separator tube (PST);** Minimum: 0.2 mL; Separate plasma from cells within 1 hour of collection; Transfer 1 mL plasma to a **standard false-bottom aliquot tube; Note: Orange-capped tubes are not acceptable;** Separate specimens must be submitted when multiple tests are ordered; Frozen *OR* **1 mL plasma from a sodium heparin (light green) plasma separator tube (PST);** Minimum: 0.2 mL; Separate plasma from cells within 1 hour of collection; Transfer 1 mL plasma to a **standard false-bottom aliquot tube; Note: Orange-capped tubes are not acceptable;** Separate specimens must be submitted when multiple tests are ordered; Frozen	Effective immediately
Vitamin B1, Whole Blood	B1VIT	**Specimen Requirement:** 3 mL whole blood in a sodium or lithium heparin green top tube; Minimum: 0.6 mL; Transfer 3 mL whole blood to a **standard false-bottom aliquot tube** and freeze immediately; **Note: Orange-capped tubes are not acceptable; Separate specimens must be submitted when multiple tests are ordered;** Critical Frozen *OR* 3 mL whole blood in an EDTA lavender top tube; Minimum: 0.6 mL; Transfer 3 mL whole blood to a **standard false-bottom aliquot tube** and freeze immediately; **Note: Orange-capped tubes are not acceptable; Separate specimens must be submitted when multiple tests are ordered;** Critical Frozen	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Vitamin B6	VITB6	**Special Information: Collect specimen after an overnight fast. This test is New York DOH approved. Unacceptable conditions: Any specimens other than heparinized plasma or serum. Serum separator tubes or EDTA preserved tubes. Hemolyzed specimens. Specimens not protected from light.** **Clinical Information: Use for nutritional assessment of vitamin B6.** The biologically active form of vitamin B6, pyridoxal 5-phosphate, is measured in this assay. Pyridoxal 5-phosphate measured in a specimen collected following an 8 hour or overnight fast accurately indicates vitamin B6 nutritional status. Non-fasting specimen concentration reflects recent vitamin intake. **Specimen Requirement:** 1 mL plasma from a sodium or lithium heparin green top tube; Minimum: 0.5 mL; Place specimen on ice after draw; Collect after an overnight fast; Separate plasma from cells **within 1 hour of collection** and freeze; Protect specimen from light; **Use amber transport tubes; Frozen** *OR* **1 mL plasma from a sodium heparin (light green) plasma separator tube (PST);** Minimum: 0.5 mL; Place specimen on ice after draw; Collect after an overnight fast; Separate plasma from cells **within 1 hour of collection** and freeze; Protect specimen from light; **Use amber transport tubes; Frozen** *OR* 1 mL serum from a red top tube with no additive; Minimum: 0.5 mL; Place specimen on ice after draw; Collect after an overnight fast; Separate serum from cells **within 1 hour of collection** and freeze; Protect specimen from light; **Use amber transport tubes; Frozen** *OR* **1 mL plasma from a lithium heparin (light green) plasma separator tube (PST)**; Minimum: 0.5 mL; Place specimen on ice after draw; Collect after an overnight fast; Separate plasma from cells **within 1 hour of collection** and freeze; Protect specimen from light; **Use amber transport tubes; Frozen** **Stability:** Ambient: After separation from cells: Unacceptable Refrigerated: After separation from cells: **3 days** Frozen: After separation from cells: 2 months	Effective immediately

New Tests

Test Name	Order Code	Change	Effective Date
Carbapenem Resistance Gene PCR	CRGPCR	**Special Information:** This test will be performed on rectal swabs collected in Amies or Stuart's transport media. Unacceptable specimens include: any swab that is highly soiled, wooden swabs, wire swabs, gel swabs, dry swabs, charcoal swabs, calcium alginate swabs, and swabs collected in transport media other than Amies or Stuart's. Specimens should be kept at room temperature (15–28 °C) and must be received within 5 days of collection. Rectal swabs stored/transported at refrigerated or frozen temperatures will be rejected. **Clinical Limitation:** A negative result does not preclude the presence of bacteria with carbapenem resistance due to mechanisms not detected by the assay (e.g., efflux pumps, porin mutation, cephalosporinase production). Mutations in primer or probe binding regions may affect detection of KPC, NDM, VIM, OXA-48 and IMP variants, resulting in a false negative result. The claimed limit of detection (LoD) for each resistance gene is 779 CFU/swab for KPC, 251 CFU/swab for NDM, 306 CFU/swab for IMP, 815 CFU/swab for VIM, and 154 CFU/swab for OXA-48. Variants detected by wet testing were KPC-2,3,4; NDM-1,2,4,5; VIM-1,2,4,10,19; OXA-48, 181, and IMP-1, 2, 4, 6, 10, 11. Additional variants were not tested but are predicted to be detected based on in silico analysis. IMP-7, IMP-13, and IMP-14 sequences are not detected by the Xpert Carba-R assay. Interference with the assay may occur with barium sulfate and Pepto-Bismol, or 0.25% w/v fecal fat. The detection of KPC, NDM, VIM, OXA-48, and IMP in rectal specimens may be from organisms other than Enterobacteriaceae, P. aeruginosa, and A. baumannii. **Clinical Information:** Performed on rectal swabs to detect intestinal colonization with carbapenem non-susceptible bacteria. This test detects and differentiates resistance genes (IMP, VIM, NDM, KPC, OXA-48) that are associated with carbapenemase production. The test is intended to aid in the prevention and control of infections caused by carbapenemase-producing bacteria in healthcare settings. Testing on rectal swabs is performed 7 days per week, 24 hours per day with a 4–6 hour TAT after receipt in Microbiology. The assay may also be performed on pure culture isolates of Enterobacteriaceae, Acinetobacter baumannii, or Pseudomonas aeruginosa with a 48 hour TAT due to subculture requirements. **Specimen Requirement:** One rectal swab in Amies or Stuart's media without charcoal; Collect specimen with dual swab: BBL Culture swab in liquid Stuart's medium or Copan swab in liquid Amies medium; Both swabs are made by Copan; Swabs in gel or other transport medium, dry swabs, and swabs with wooden shaft will be rejected; Ambient *OR* One pure culture isolate of organism submitted on sterile culture media; Ambient **Stability:** Ambient: 5 days Refrigerated: Unacceptable; will be rejected Frozen: Unacceptable; will be rejected **Methodology:** Polymerase Chain Reaction (PCR) **Reference Range:** Carbapenem Resistance Gene IMP Not Detected VIM Not Detected NDM Not Detected KPC Not Detected OXA48 Not Detected **Days Performed:** 7 days per week **Reported:** 1 day **CPT:** 87798 x 2 **Price:** $240.00	5/2/17
Chromosome Analysis with Reflex AML FISH panel	CHRAML	**Note:** *This test was previously announced in the March 2017 Technical Update.* **Test Name:** Previously Chromosome Analysis with Reflex AML FISH **Price:** $1129.00 (non-discountable)	Effective immediately
FISH for Aggressive B-Cell Lymphoma on Bone Marrow or Blood	FABCFP	**Note:** *This test was previously announced in the March 2017 Technical Update.* **Price:** $1285.00 (non-discountable)	Effective immediately

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
FISH for BCL2 on Bone Marrow or Blood	BCL2FH	**Note:** *This test was previously announced in the March 2017 Technical Update.* **Price:** $680.00 (non-discountable)	Effective immediately
IDH1/IDH2 Mutation, FFPE Tissue	IDH12F	**Special Information:** Protect from excessive heat. Ship in cooled containers during summer months. For FFPE specimens, include surgical pathology report. Tissue block will be returned after testing. Unacceptable conditions: No tumor in tissue. Specimens fixed/processed in alternative fixatives (alcohol, Prefer) or heavy metal fixatives (B-4 or B-5). Decalcified specimens. This test is New York DOH approved. **Clinical Information:** IDH1/IDH2 mutational status is a prognostic marker in individuals with low- and high-grade gliomas. Aid in distinguishing a primary from a secondary glioblastoma. **Specimen Requirement:** One formalin-fixed paraffin-embedded (FFPE) tissue block; FFPE tumor tissue; Formalin fix (10% neutral buffered formalin) and paraffin embed tissue; Transport block in a tissue transport kit (ARUP supply #47808); Include surgical pathology report; Ambient *OR* Four unstained 5-micron tissue slides; Minimum: 3 unstained 5-micron slides; Transport slides in a tissue transport kit (ARUP supply #47808); Ambient **Stability:** Ambient: Indefinitely Refrigerated: Indefinitely Frozen: Unacceptable **Methodology:** Polymerase Chain Reaction/Sequencing **Days Performed:** Sunday, Tuesday, Thursday **Reported:** 13–18 days **CPT:** 81403 x 2, 88381 x 1 **Price:** $546.00 (non-discountable)	5/15/17

Fee Reductions

Test Name	Order Code	List Fee	CPT Code	Effective Date
G-6-PD Quantitative	G6PDQT	$48.00	82955	7/11/17

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Alpha Globin (HBA1 & HBA2) Sequencing	HBA12B	This test will no longer be available.	5/15/17
CMV PCR, Bone Marrow	CMVBM	This test will no longer be available. Suggest ordering CMV by PCR, CSF/FLD/Tissue/Bone Marrow (CMVCSF)	5/15/17
Platelet Antibody Screen	PLTAB3	This test will no longer be available. Suggest ordering Platelet Assoc. Abs. IgG, IgM (PLTABD).	6/29/17